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Introduction of a measurement set-up to monitor the pressure applied during hand-held ultrasound elastography

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Abstract

Shear wave elastography may produce misleadingly high values if too much pressure is applied during the imaging process. However, in clinical routine there is presently no way to monitor the pressure applied during the measurements. In this work we introduce a novel measurement set-up which can directly be attached to an ultrasonic imaging transducer and allows to observe the applied pressure in real time. The introduced set-up supports free-hand imaging according to the clinical standard. We tested the set-up by carrying out SWE under varying pressures on ***ex vivo*** animal tissue. The SWE values increased with pressure as was expected. Thus, the introduced set-up is a possible solution to measure the applied pressure in real-time.

Keywords: Ultrasound, Pressure, Elastography, Shear Wave Elastography, Cancer, Breast Cancer, Phantoms

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Introduction

Supersonic shear wave elastography (SWE) is an ultrasound (US) imaging technique used to visualise and measure the elasticity of tissue. Already the first clinical SWE study showed that applied pressure influences the SWE measurements and recommended avoiding the application of pressure during the procedure (Berg et al., 2012). However, SWE imaging is carried out manually and it is thus, difficult to completely avoid pressure applied by the clinician. Even if the clinician deliberately relieves her or his pressure, the weight of the probe may still cause some pressure to be applied. Hence, it is reasonable to state that application of a constant and reproducible pressure is impossible to achieve in clinical practice.

Some previous studies showed the influence of applied pressure on measurement of SWE values for breast tissue (Barr and Zhang, 2012; Wojcinski et al., 2013; Bernal et al., 2016; Sayed et al., 2014). Their set-up is not applicable in clinically routine SWE imaging, where the patient is in the supine position. In response to the needs, capabilities and limitations of previous work, here we introduce a novel measurement device, which can be attached around an US SWE transducer to monitor the applied pressure in real time with as little impact as possible onto the clinical protocol.

Materials and Methods

The novel measurement device has two requirements to aid clinical routine. First, it should be easily attached around the imaging probe to allow SWE measurements to be made in its presence and absence to avoid bias in clinical practice. Second, the attachment and removal processes should take a maximum of a few minutes to allow application in routine clinical practice.

Three observers (2 radiologists, 1 radiographer, all with at least 5 years' experience in breast sonography and 3 years' experience in SWE imaging) were asked to apply pressure with the SWE probe on a commercial phantom (CIRS, Model 059, Norfolk, VI, USA) similar to what they would apply in clinical routine. The phantom was placed on a calibrated scale and the increase in weight was monitored. The applied pressure p was calculated over the transducer's surface (61 mm x 8 mm, $A = 488$ mm^2). The applied p differed by at least 0.2 N / 0.4 kPa for the three evaluated observers. Therefore, the sensor should enable an accuracy of 0.1 N / 0.2 kPa. The upper limit of the measurement range was estimated after discussion with an expert radiologist with more than 20 years' experience in US breast imaging and was, accordingly, set to 10 N or 20 kPa.

The measurement device is realised as a double shell around the SWE probe **to avoid any damage of the probe. The pressure is** measured between these shells. **The inner shell (Fig. 1a) is attached directly to the SWE probe, while the outer shell (Fig. 1b) is moveable relative to the inner shell via a sliding system. A spring pushes the outer shell upwards onto the pressure sensors, which are attached to the inner shell. Thus, the device introduced here measures a reduction rather than an increase in applied pressure to allow the measurement of unladen pressure**.

The shells were created by 3D printing using acrylonitrile butadiene styrene (ABS) plastic. This allowed freedom in the design while keeping production costs low. Four springs press the outer shell upwards with a force of 10 N, i.e. the maximum of the measurement range defined. Two strain-gauge sensors (FSR402, Interlink Electronics, Los Angeles, CA, USA) are positioned on each side of a step leading around the inner shell and convert the applied force into a decrease in electrical resistance and thus, a decrease in voltage drop. The sensors are positioned out of alignment with the centre to allow the measurement of any drift if the pressure is not applied exactly vertically. Careful handling of the sensors was required as they broke easily. The outer shell presses against the pressure sensors. When the SWE probe touches the tissue the pressure on the sensors decreases and a lower signal is produced.

Measurements with and without the SWE probe included within the shells were calibrated to validate the correlation between the applied pressure and the signal outputs. The calibration was performed with the device placed directly onto a calibrated scale. The measurements on the ***ex vivo*** samples were performed according to routine clinical practice but with a calibrated scale underneath. The scale used for the measurements was identical with the one used in the calibration process. The preloaded pressure was increased from 0 g / 0 N / 0 kPa to 1 kg / 10 N /20 kPa with increments of 100 g /1 N /2 kPa. For each preload, five measurements were recorded and averaged for evaluation.

Ex vivo samples including chicken breast, porcine belly, boiling beef and bovine udder were investigated. The ***ex vivo*** tissues were obtained through a local slaughterhouse and no additional harm was applied to any animal. All images were obtained using the Aixplorer US system (SuperSonic Imagine, France), frequency range 4 - 15 MHz, axial resolution 0.3 - 0.5 mm, lateral resolution 0.3 - 0.6 mm, elasticity range 0 - 300 kPa. The SWE measurements were performed using a circular region of interest (ROI) with a diameter of 3 mm. The ROI was positioned at the stiffest part of the image excluding artefacts. This procedure is equivalent to the standard imaging process of breast imaging, i.e. our aimed application, in clinical practice. All images were obtained by three observers (two radiologists with at least 5 years' experience in breast US imaging and a trained engineer). Each measurement started with minimal preload pressure, which was then increased until either the test object was damaged, the image quality was insufficient or the maximum measurement range was reached. Although the aim was to start with 0 N / 0 Pa, this was impossible in practical terms as contact was required to enable transmission of the US into the test object. Thus, the minimum pressure applied was 0.2 N / 0.4 kPa. For each setting three measurements were obtained. These measurements were averaged and evaluated using spread-sheet functions (Microsoft Excel 2013).

Results

The measurement set-up was calibrated with and without the SWE probe. Both sensors achieved good reproducibility if the device was used alone without the probe **(mean deviation from the average for sensors 1 and 2: 0.14 V and 0.40 V)**. However, if the probe was attached to the pressure measurement device, the reproducibility was reduced **(mean deviation from the average for sensors 1 and 2: 0.76 V and 0.73 V)**. The position of the imaging probe cable was observed to have an influence on the reproducibility. The measurement set-up worked well on the ***ex vivo*** tissues and handling was similar as in the clinical imaging protocol. Figure 2 shows the correlation of the elasticity parameter mean elasticity E_{mean} for all ***ex vivo*** samples. The E_{mean} and E_{max} values increased approximately linearly with an increasing pre-load, whereas no clear correlation could be observed in the SD values. Figure 3 shows the SWE image in the bovine udder for the minimum (0.2 N) and an intermediate (3 N) pre-load.

Discussion

Ultrasonic SWE imaging is a hand-held imaging modality and a complete avoidance of applied pressure is impossible. Hence, the pressure applied by the ultrasound probe during clinical assessment should be considered to further standardize the diagnostic image evaluation. The demonstrated device enables monitoring of the external pressure applied in real time by an observer or clinician during SWE imaging. The **measurements are** sensitive to the weight of the probe and the cable, which was not considered when designing the device. The design could be improved in future by taking this into account. The present device was made of plastic by 3D printing. Our approach provided relatively poor physical accuracy and the material is relatively soft. **We did not observe any influence from handling the outer shell, e.g. squeezing it, on the measurements.** Better results might be achieved if a 3D printing set-up of higher quality was used or if the mechanical components of the device were made of aluminium. However, this would have increased its cost very significantly.

Our study showed that even amongst observers who apply the same imaging protocol a bias in the SWE measurements may occur. Thus, real-time feedback to the observer would be helpful to standardise the imaging procedure. Definition of a pressure**,** which should be applied for the best clinical performance**,** or adjusted cut-off thresholds for benign / malignant differentiation would be of interest in the future. Additionally, monitoring the applied pressure and consequential changes in elasticity during clinical examination might also improve the benign / malignant differentiation, based on the correlation with malignancy noted in previous studies (Krouskop et al., 1998; Barr and Zhang, 2012; Syversveen et al., 2012; Sayed et al., 2014; Bernal et al., 2016). Hence, real-time measurements of the applied pressure might give clinicians a novel SWE biomarker.

Previous studies introduced different pressure application or measurement arrangements such as (Barr and Zhang, 2012; Syversveen et al., 2012; Sayed et al., 2014; Bernal et al., 2016; Bell et al., 2016, 2014; Gilbertson and Anthony, 2015)**.** However, to the best of the authors' knowledge only the set-up introduced by Gilbertson and Anthony (2015) permits **a quantitative analysis of the applied pressure** for hand-held US imaging and could thus**,** be applicable to breast cancer imaging. This set-up requires a special handling and is relatively heavy (about 700 g, mass of an US probe < 100 g)**, whereas the introduced set-up is much lighter (about 220 g). Although this nearly triples the weight of the transducer during the measurement, the** device introduced in this work has amongst the introduced solutions the lowest impact onto the clinical imaging protocol and has thus, the highest potential for transition into clinical routine.

A clinical trial was not possible with the device that has been described **as**

the attachment and removal process of the set-up is still too time consuming. Measurements were performed only using ***ex vivo*** samples. **Inaccurate SWE values might be derived from *ex vivo* tissues due to the lack of perfusion. Nevertheless, this study shows that a clinical study using the introduced measurement set-up would be feasible.** This has potential to improve not only the benign / malignant differentiation of solid breast lesions but also to improve prediction of lesion behaviour and the use of personalised therapy.

Conclusions

SWE increases with applied pressure and inter-observer variations in the clinical application of SWE may thus**,** bias the diagnostic performance of SWE. Hence, real time monitoring of the applied pressure would be clinically useful. The measurement device introduced here is the first step towards introducing a method for examining the pressure applied during clinical examinations. The results from a preliminary ***ex vivo*** study showing an approximate linear increase in elasticity are promising. However the device design should be improved to enhance its clinical applicability.

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Figure Captions

Figure 1: Two shells are attached around the ultrasound probe: a) an inner and b) an outer shell. Two pressure sensors are attached to the inner shell. The observer presses the outer shell onto the sensors.

Figure 2: The mean elasticity E_{mean} increases with pressure in the ***ex vivo*** samples **(correlation of 0.997, 0.981, 0.135 and 0.935 for the chicken breast, porcine belly, boiling beef and the bovine utter)**.

Figure 3: SWE image of a bovine udder with a) minimal, i.e. 0.2 N, and b) intermediate, i.e. 3 N, pre-load. **The E_{mean} values were 77 kPa and 230 kPa.**